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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/776,454 | 02/02/2001 | Gregorio del Val | 2001-0705 | 9327 |

20872 7590 05/20/2003
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| EXAMINER |
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WHITEMAN, BRIAN A

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| ART UNIT | PAPER NUMBER |
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1635

DATE MAILED: 05/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------------------|-------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/776,454 | VAL ET AL. |
| | Examiner: Brian Whiteman | Art Unit 1635 |

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 February 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-8, 10, 12 and 22-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 1, 2, 6-8, 10, 12, 22, 23, 27-33 and 37-41 is/are allowed.
- 6) Claim(s) 3-5, 24-26 and 34-36 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) Interview Summary (PTO-413) Paper No(s). 18.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

DETAILED ACTION

Final Rejection

Claims 1-8, 10, 12, and 22-41 are pending.

Applicants' traversal, the amendment to claims 1, 2, 3, 5, 6, 7, 8, 10, 12, 22, 23, 24, 26, 27, 28, 29, 30, 31, 32, 33, 34, 36, 37, and 39-41, in paper no. 16 filed on 2/21/03 is acknowledged and considered.

Claim Objections

Applicant's arguments, see paper no. 16, filed on 2/21/03, with respect to the objection have been fully considered and are persuasive. The objection of claims 1, 22, and 32 has been withdrawn because of the amendment to claims 1, 22, and 32.

Claim Rejections - 35 USC § 112

Applicant's arguments, see paper no. 16, filed on 2/21/03, with respect to the 112 first paragraph rejection have been fully considered and are persuasive. The rejection of claims 2, 23-31, and 33 has been withdrawn because of the amendment to the claims. However, in view of the amendment to claims 3, 5, 24, 26, 34, and 36, a rejection under 112 first paragraph is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 3, 4, 5, 24, 25, 26, 34, 35, and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claims 3, 24, and 34 filed on 2/21/03 introduce new subject matter into the application. The application and the originally filed claim as a whole are directed to a method of testing the allergenicity of a heterologous protein produced by a plant that has been genetically modified to produce the protein comprising using a first extract comprising a mixture of plant proteins and the heterologous protein and a second extract comprising the same proteins as the first extract, but lacking the heterologous protein.

The original specification did not disclose using a second extract obtained from a genetically modified plant. There is no page cited for support of the amended claim. Page 5, lines 24-26) states, “in a preferred embodiment, the extract is obtained from a transgenic plant.” It is apparent that the applicants at the time the invention was made did not intend or contemplate using a second extract obtained from a genetically modified plant as part of the disclosure of their invention. There is no evidence in the specification that the applicants were possession of second extract obtained from a genetically modified plant in the amended claim and claims dependent thereof, as it is now claimed, at the time the application was filed.

Amended claims 5, 26, and 36 filed on 2/21/03 introduce new subject matter into the application. The application and the originally filed claim as a whole are directed to a method of testing the allergenicity of a heterologous protein produced by a plant that has been genetically

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modified to produce the protein further comprising wherein step d) is carried out by applying the first extract to a dog sensitized with the second extract.

The original specification did not disclose wherein step (a) further comprises sensitizing the newborn dog with the second extract by applying the second extract to the skin of the newborn dog. The page cited (page 12, lines 22-33) for support of the amended claim does not support the step. The page cited is directed to three types of extracts, which can be used for sensitizing a newborn dog from an atopic colony. The originally filed claim was directed to applying the first extract to a dog sensitized with the second extract and not sensitizing the dog with both the first and second extracts. Furthermore, page 12, cites Example 2 and Example 2 does not support sensitizing the newborn dog with both the first and second extracts by applying the second extract to the skin of the newborn dog. It is apparent that the applicants at the time the invention was made did not intend or contemplate sensitizing the newborn dog with both the first and second extract as part of the disclosure of their invention. There is no evidence in the specification that the applicants were possession of the claimed method in the amended claims and claims dependent thereof, as it is now claimed, at the time the application was filed.

Applicant's arguments with respect to claims 3, 4, 5, 24, 25, 26, 34, 35, and 36 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments, see paper no. 16, filed on 2/21/03, with respect to the rejection(s) of claims 1-8, 10, 12, 22-41 under 112 second paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Conclusion

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER